REMARKS

Claims 1-6 are pending in the instant application. Claims 1-6 have been rejected. Claims 1, 2, 3, 4, 5 and 6 have been amended. Support for these amendments is provided throughout the specification and in particular at page 2, lines 2 through 5, page 5, lines 8 through 17, page 10, lines 5-7, Example 1 at page 10 and Example 4 at page 13. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Objection to Specification

The Examiner suggests that the application does not contain an Abstract. It is respectfully pointed out, however, that this is a National Stage Application of PCT/US00/04703 and the Abstract is provided on the cover page of the application. However, in an earnest effort to be completely responsive, Applicants are providing herewith a copy of this Abstract on a separate sheet of paper as page 17. No new matter is added by this amendment. Withdrawal of this objection is respectfully requested in light of this submission.

II. Rejection of Claims 1-6 under 35 U.S.C. 112, first paragraph - Lack of Enablement

Claims 1-6 have been rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has acknowledged that the specification provides extensive teachings, specific guidance, and working examples pertaining to the creation of a transgenic mouse whose genome comprises a homozygous full-length human elastin promoter operably linked to a nucleotide sequence encoding a reporter protein, fibroblasts obtained from the same mouse, and methods of the mouse and/or fibroblasts for identifying compounds capable of inhibiting cutaneous photodamage or oxidative damage. However, the Examiner suggests that the specification fails to provide any relevant teachings or specific guidance with regard to the generation of other transgenic mice embraced by the claims and their corresponding phenotypes.

Applicants respectfully traverse this rejection.

Applicants respectfully disagree with the Examiner's suggestion that the extensive teachings, specific guidance, and working examples of the present invention pertain only to the creation of a transgenic mouse whose genome comprises a homozygous full-length human elastin promoter operably linked to

a nucleotide sequence encoding a reporter protein, fibroblasts obtained from the same mouse, and methods of the mouse and/or fibroblasts for identifying compounds capable of inhibiting cutaneous photodamage or oxidative damage. The Examiner is respectfully directed to page 3, lines 22-30, page 5, lines 6-13, page 7, lines 11-24 and Example 1 wherein extensive teachings, specific guidance and working examples of transgenic mice whose genome comprises a homozygous truncated human elastin promoter activated by UV radiation and operably linked to a nucleotide sequence encoding a reporter protein are also provided. These teachings are clearly enabling for one of skill in the art to make and use these transgenic mice as well.

Thus, in accordance with the enablement provided by the instant specification and in earnest effort to advance the prosecution of this case and to address concerns raised by the Examiner regarding the breadth of the claims embracing heterozygous and chimeric mice, Applicants have amended the claims to clarify that the transgenic mice have a genome comprising a homozygous full length human elastin promoter or a truncated human elastin promoter activated by UV radiation operably linked to a nucleotide sequence encoding a reporter protein.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph is respectfully requested in light of the amendments to the claims and the above remarks.

III. Rejection of Claims 1-6 under 35 U.S.C. 112, first paragraph - Written Description

Claims 1-6 have been rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. Specifically, the Examiner suggests that while the specification discloses a full-length human elastin promoter, it does not disclose any truncated forms of human elastin promoter. Further, the Examiner suggests that there is no evidence of record with respect to either a relationship or a known relationship between the structure of any human elastin promoter and the claimed truncated human elastin promoter or the claims truncated human elastin promoter even having the biological activity of a full length elastin promoter.

Applicants respectfully disagree.

Contrary to the Examiner's suggestion, multiple truncated human elastin promoters activated by UV light are taught at page 5, lines 8 through 13. Further, results from experiments with mice expressing a truncated human elastin promoter are described at page 7, lines 11-25, and production of such mice is described

in Example 1. As taught at page 3, lines 22-26 and page 7, lines 15-21, a 20 to 30 fold increase in promoter activity was observed in mice of the present invention with a truncated human elastin promoter, thus demonstrating that these mice actually provide a more sensitive model as compared to mice expressing the full length promoter.

Accordingly, the Examiner's basis for this rejection of lack of written description is incorrect as the specification teaches multiple truncated human elastin promoter and provides evidence of a known relationship between the structure of any human elastin promoter and the claimed truncated human elastin promoter and evidence of the truncated human elastin promoter having even better biological activity than the full length elastin promoter well.

Further, in an earnest effort to advance the prosecution and in accordance with teachings at page 5, lines 8-13, Applicants have amended the claims to clarify that truncated elastin promoter is activated by UV or solar simulating radiation.

Withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested in light of the above remarks and the amendments to the claims.

IV. Rejection of Claims 1-6 under 35 U.S.C. § 112, second paragraph

Claims 1-6 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In particular, the Examiner suggests that claim 1 is indefinite for inclusion of the phrase "capable of expressing an elastin promoter." The Examiner suggests that it is well known in the field of Molecular Biology that a promoter is not expressed but rather a promoter directs expression of a coding nucleotide sequence. Further the Examiner suggests that the language "capable of" implies a latent potential but does not necessarily require function.

Thus, in an earnest effort to advance the prosecution of this case, Applicants have amended the claims to clarify that the homozygous full length or truncated human elastin promoter is operably linked to a nucleotide sequence encoding a reporter protein and that it is expression of the reporter protein which is measured to determine promoter activity. Support for this amendment is provided in the specification at page 5, lines 13-17, page 10, lines 5-7, and Example 4 at page 13.

V. Rejection of Claims 1-5 under 35 U.S.C. § 102(b)

Claims 1-5 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Bernstein et al. (U.S. Patent 5,648,061). Claims 1-5 have also been rejected under 35 U.S.C. § 102(b) as being anticipated by Bernstein et al. (J. Invest. Dermatol. 1995 105:269-273). The Examiner suggests that each of these references teach a transgenic hairless mouse capable of expressing a full-length or truncated human elastin promoter and fibroblast cultures obtained from the same transgenic mouse. The Examiner further suggests that the references teach methods of identifying compounds capable of inhibiting cutaneous photodamage in either the same mouse or fibroblasts obtained from the same mouse and the components of the system of claim 5.

Applicants respectfully disagree.

Contrary to the Examiner's suggestion, neither Bernstein et al. (U.S. Patent 5,648,061) nor Bernstein et al. (J. Invest. Dermatol. 1995 105:269-273) teach or even suggest a transgenic hairless mouse capable of expressing a truncated human elastin promoter. All teachings of these reference relating a full length human elastin promoter.

Accordingly, in an earnest effort to advance the prosecution of this case and to clearly distinguish the present invention

from any prior art teachings, Applicants have amended the claims to state that the transgenic mouse or cell culture has a genome comprising a truncated human elastin promoter activated by UV radiation operably linked to a nucleotide sequence encoding a reporter protein. Since neither of the cited prior art references teaches a transgenic mouse or cell culture with a truncated human elastin promoter, these references cannot anticipate the claims as amended and claims dependent there from. See MPEP § 2131.

Withdrawal of these rejections under 35 U.S.C. 102(b) is therefore respectfully requested.

VI. Obviousness-type Double Patenting Rejection of Claims 1-5

Claims 1-5 have been rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent 5,648,061. The Examiner has acknowledged that the conflicting claims are not identical but suggests that they are not patentably distinct from each other because they both embrace a transgenic mouse comprising a human elastin promoter, fibroblast cultures obtained from the same transgenic mouse, and methods of identifying compounds capable of inhibiting cutaneous photodamage using either the same mouse or fibroblasts obtained there from.

However, as discussed in Section V, supra, the claims have been amended and are no longer drawn to a transgenic mouse or cell culture comprising a full length human elastin promoter as taught by U.S. Patent 5,648,061, but rather a truncated human elastin promoter. As also discussed in Section V, supra, U.S. Patent 5,648,061 does not teach nor does it suggest use of a truncated human elastin promoter. Accordingly, the claims as amended are clearly patentably distinct from U.S. Patent 5,648,061 and withdrawal of this obviousness-type double patenting rejection is respectfully requested.

VII. Conclusion

Applicants believe this reply is completely responsive to the Office Action of record. Reconsideration and allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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